

**Maternal and Child Health Improvement Projects  
Abstract**

**Project Title:** Newborn Screening Using Tandem Mass Spectrometry FELSI Project

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**Project Period:** 3 Years      **From:** 6/1/2001 to 5/31/2004

**Purpose:** To use a multi-state collaboration to research, identify strategies and develop materials for addressing the ethical, legal, social and financial issues surrounding the use of Tandem Mass Spectrometry (MS/MS) for newborn screening (NBS) of a cultural and ethnically diverse population.

**Challenges:** Challenges facing this project include: maximizing each state's benefits from the project, while minimizing the resources required from each state to complete the project's activities; choosing the most useful communication strategies for various project tasks (i.e. innovative methods such as web page message boards vs. traditional strategies such as telephone calls and face-to-face meetings); and, developing educational products that meet the needs of both consumers and state newborn screening programs.

**Goals and Objectives:**

Goal 1)	Data on cultural and ethnically diverse views on NBS using MS/MS are available.
Objectives:	Gather input about using MS/MS for NBS via community consultations.
Goal 2)	Accurate, culturally appropriate, translated, and understandable educational materials and guidelines on NBS using MS/MS for families and providers are available.
Objectives:	Develop, test, refine, and disseminate education materials for consumers and health care providers regarding using MS/MS for NBS. Translate English educational materials into at least 3 languages.
Goal 3)	Families receive accurate, culturally appropriate, translated, and understandable informed consent information about NBS research.
Objectives:	Develop model informed consent language for NBS using MS/MS and provide access to consent form.
Goal 4)	Accurate and culturally appropriate information is provided by healthcare providers about ethnocultural differences in the manifestations and frequencies of disorders detectable by MS/MS
Objectives:	Research current information, collaborate with Project 2 about new findings, and disseminate information to healthcare providers via education material developed in Goal 3.
Goal 5)	Protect children from unnecessary and/or unethical genetic testing.
Objectives:	Based on results of community consultation, develop and disseminate model legislation to regulate testing of minor children for late onset diseases.

**Methodology:** A Project Steering Committee will prioritize, approve and oversee project activities. The Steering Committee will consist of representatives from each of the participating states. Four workgroups (Research, Education, Legal/Legislative and Evaluation) will complete the project activities. The Research Workgroup will gather opinions from ethnically and culturally diverse communities about implementing MS/MS for NBS using focus groups and key informant interviews. Consumer input will also be gathered via the internet through the project website. The data obtained will be analyzed and reported. The other workgroups will use the research data to develop and evaluate projects assigned to their workgroup. The Education Workgroup is responsible for developing educational strategies for consumers and healthcare providers. The Legal and Legislative Workgroup will develop model legislation to address the FELSI issues surrounding the addition of MS/MS to NBS. The Evaluation Workgroup is responsible for development and implementation of evaluation strategies throughout the project cycle.

**Evaluation:** Evaluation consultants will assist the Evaluation Work Group to develop evaluation measures for the project. Qualitative evaluation of participant, consumer and healthcare provider satisfaction with educational materials will be obtained during the project. To maximize consumer and provider satisfaction with the materials produced, a prototyping model will be used for developing materials. Measurement of the effectiveness and appropriateness of the educational materials, legislative model language and other project activities will be tracked using contact information, pre and post tests of knowledge gaps and knowledge gained, and number of providers using the products developed. Process evaluation will be done to monitor progress against the activity timeline. The project will also complete a summative analysis that will include lessons learned from the project and suggestions for future projects.

**Experience  
To Date:**

- 1) Hawaii, Oregon, and California provide the three models of newborn screening in the country (contracted screening to regional laboratory, regional laboratory, and in state only screening).
- 2) Membership of the California and Hawaii State Genetics Coordinators on the HRSA/American Academy of Pediatrics Newborn Screening Task Force and subcommittees.
- 3) Core and participating states successfully collaborated for the past 12 years on regional genetics networks (PSRGN and PacNoRGG) including addressing emerging technologies and consumer and health professional education
- 4) In addition to newborn metabolic screening, Hawaii has an established universal newborn hearing screening program (over 97% of newborns screened for hearing in 1999). The other participating states are in the process of implementing their newborn hearing screening programs.

**Text of  
Annotation:**

This multi-state collaborative effort will address the financial, ethical, legal, and social issues surrounding using Tandem Mass Spectrometry (MS/MS) for Newborn Screening (NBS). The goals of the project are: 1) Obtain culturally and ethnically diverse views about using MS/MS for NBS using community consultations and key informant interviews; 2) Develop education materials, informed consent and model legislative language to respond to the issues important to our communities.

**Key Words:**

Education, Financial, Focus Group, Genetics, Screening, Informed Consent, Key Informant, Legislative Language, Maternal and Child Health Bureau, Newborn Screening, State Health Agencies; Tandem Mass Spectrometry, Testing